UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM, Plaintiffs, -vs- GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, JOHN DOES 1-10, Defendants.	CIVIL ACTION NO. 07-CV-1359 (GEB)(ES) Oral Argument Requested

MOTION TO STRIKE PLAINTIFFS' LIABILITY EXPERTS

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PRELIMINARY STATEMENT

Plaintiffs proffer Dr. Charles Strom ("Strom") as their chief liability expert witness against Genesis Genetics Institute, LLC ("Genesis") and Dr. Mark R. Hughes ("Hughes"). Plaintiffs proffer Dr. Garry Cutting ("Cutting") as their chief liability expert witness against New York University School of Medicine and New York University Hospitals Center (collectively "NYU"). Inter alia, he has rendered criticisms against Genesis and Hughes. The factual assumptions of Strom and Cutting against Genesis and Hughes which are based upon their understanding of the applicable standard of care are unsupported—indeed, fundamentally contradicted—by the record.

Further, Strom is not qualified as an expert witness as to the standard of care existing as to preimplantation genetic diagnosis ("PGD") as it existed in the United States in 2004, when the incident(s) forming the subject matter of this litigation arose, for the reason that he had long since ceased to be actively involved in PGD by that time.

Cutting is not qualified as an expert witness as to the standard of care existing as to PGD as it existed in the United States in 2004, when the incident(s) forming the subject matter of this litigation arose. He has never been routinely involved in the practice of PGD; and such limited involvement as he has had, consisting of doing two (2) PGD cases, took place between 2007 and 2010, well after the incidents occurred that are the subject of this lawsuit.

Accordingly, this Court should strike the opinions and testimony of Strom and Cutting under FRE 702 and *Daubert* as unsupported by fact, unreliable, misleading, and lacking "fit" to the facts of this case.

STATEMENT OF FACTS

Before they were married, plaintiffs Menachem and Chaya Grossbaum each learned that they were carriers of a gene for cystic fibrosis, a congenital condition. After they married, they sought out the fertility clinic at defendant NYU for in vitro fertilization ("IVF"), in the hope of reducing the risk of giving birth to a child afflicted with cystic fibrosis to some percentage less than the naturally-occurring 25%. (Ex. 8 (Deposition of Menachem Grossbaum, 3/12/09) at 18:15 - 25.).

IVF is a process in which several eggs are harvested from the mother. Each egg is then fertilized with one sperm from the father. In typical IVF, one or two of the eggs are implanted into the mother on the fifth day of their existence, the selection of the eggs being dependent upon the extent of their cellular development. Eggs most likely to result in a successful pregnancy contain eight cells. IVF is typically utilized to overcome fertility problems. If, however, a couple is seeking to avoid a congenital problem, PGD is superimposed upon the IVF process. (Ex. 13 at CG081 - CG085, ¶ 1.) (Ex. 13 at CG081-CG084, ¶ 5.) (Ex. 13 at CG081-084, ¶ 6.) (Ex. 13 at CG081-084, ¶ 10.) (Ex. 13 at CG081-084 (preamble) (Ex. 13 at CG089-092.).

Preimplantation genetic diagnosis, as its name implies, involves the diagnosis before implantation of embryos of cells biopsied from embryos to determine whether the cells are affected with the disease or condition sought to be prevented, whether they are carriers of the condition, or whether they are unaffected. One cell is biopsied from each of the embryos created in the IVF lab, and the cells are sent to the PGD lab for analysis. After the cells are analyzed, their condition is reported to the IVF clinic; and the IVF clinic and the involved would-be parents make a decision as to which embryos, if any, will be implanted. This decision includes a genetic analysis of the biopsied cells and a quality analysis

of the embryos. (Ex. 13 at CG089-092.) (Ex. 13 at CG089-092, ¶ 3.) (Ex. 13 at CG089-092 ¶¶ 4, 5; Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23; Ex. 11 (Deposition Transcript of Dr. Frederick Liccardi, dated 3/11/09) at 62:18 - 63:17.) (Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.).

In early-to-mid 2004, when the events occurred that are the subject of this case, there were no more than eight (8) laboratories in the United States that were doing PGD in any significant volume. PGD was then, and is now, a highly sophisticated, rapidly evolving technology. There are thousands of genetic mutations; and it is necessary to devise a separate PGD test for each such mutation, customized for the couple, often in an extremely short period of time. (Ex. 1 (Deposition of Dr. Charles Strom, Vol. I, dated 5/4/10) at 112:7-8, 15-16, 18-23; 113:2-16.) (Ex. 18 at 26:17 - 25.).

There were two ways in which labs in the United States did PGD in early-to-mid 2004. All but one lab, including Genesis, performed PGD with single cell testing. One laboratory, Reproduction Genetics Institute ("RGI"), performed multiplex (or genetic marker) testing. Multiplex testing was in its infancy in the United States. It involved obtaining one embryonic cell after IVF, and then comparing the cell with cells taken from other family members of the involved couple. Various laboratories, including Genesis, were trying to develop this technology in America; but as of the dates in question, the success rate they achieved in trial runs was not sufficiently high for the technique to be used on a regular basis. (Ex. 13 at CG089-092, ¶ 4.) (Ex. 6 at ¶ 10; Ex. 5 (Expert Report of Kangpu Xu, dated 2/26/10) at 2.) (Ex. 6 at ¶ 10.) (Ex. 2 (Deposition of Mark R. Hughes, dated 5/14/10) at 49:17 - 54:20.) (*Id.*; Ex. 6 at ¶ 9, 10.).

Dr. Kangpu Xu ("Xu"), the retained liability expert for defendants Genesis and Hughes, was actively involved in the PGD laboratory at Weill Cornell School

of Medicine in New York City at the time the incidents that form the subject matter of this lawsuit took place. (Ex. 5 at 1-2.) He says:

> Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, *multiplex PCR was not the standard in 2004.* During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. *I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.* Report, p. 2. Emphasis added.

The failure rate of single cell PGD was less than five percent (5%) in early-to-mid 2004, although Genesis enjoyed a far smaller failure rate, in the area of two percent (2%) or less. The main problem with single cell testing was that it was difficult to predict allele drop out ("ADO"), a known complication in PGD. The five percent rate was quoted to the Grossbaums, and they were otherwise fully informed as to the nature and risks of PGD. (Ex. 18 at 31:3 - 13.) (Ex. 2 at 33:6 - 19; Ex. 5 at 2.) (Ex. 9 at 120:15-121:12, 171:4-172:9; Ex. 8 at 32:14-16; Ex. 16 (Deposition of Dr. Kangpu Xu, dated 5/13/10) at 100:12 - 25, 101:13 - 16, 101: 23 - 25, 102: 1 - 25, 103:1 - 5; Ex. 13 at CG093-CG097, ¶ 5, 6.).

The Grossbaums underwent IVF with NYU, and PGD with Genesis. On July 19, 2004, Genesis faxed to NYU a document addressing the potential transfer of several embryos. In this document, Genesis stated "OK for transfer" as to two of the embryos, designated as nos. 8 and 10. The document also addressed analysis of the cells biopsied from other embryos. The embryos themselves were

physically located at the NYU Fertility Clinic. Only NYU personnel, and through them the Grossbaums, had knowledge of the quality of the embryos themselves. (Ex. 13 at CG064, CG125.) (Ex. 13 at CG131 - CG134.) (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9-23.).

The determination as to the suitability of embryos for in vitro fertilization based upon the results from Genesis was made by Dr. Frederick Licciardi and embryologist Alexis Adler. Without consulting anyone at Genesis, Licciardi and Adler decided to replace embryo no. 10 with embryo no. 7. The Grossbaums concurred in this decision. On July 19, 2004, embryos no. 7 and 8 were implanted in Chaya Grossbaum. A pregnancy ensued, resulting ultimately in the birth of the infant plaintiff, Rosie Grossbaum. Rosie Grossbaum has cystic fibrosis. (Ex. 9 at 154:5 - 156:23; Ex. 13 at CG134.) (Ex. 13 at CG134; Ex. 9 at 154:13-156:6; Ex. 8 at 61:9-23.).

The plaintiffs' liability experts, Strom and Cutting, have both testified that the standard of care required that defendants Hughes and Genesis perform genetic marker, or multiplex, testing in the PGD done for the Grossbaums, and that their failure to do so was the likely proximate cause of the infant plaintiff being born with cystic fibrosis. (Ex. 24 (Expert Report of Dr. Garry R. Cutting, dated 9/29/09) at 3; Ex. 25 (Expert Report of Dr. Charles M. Strom, dated 11/12/09) at 2.) (Ex. 15 (Deposition of Dr. Garry Cutting, Vol. II, dated 11/8/10) at 283:2 - 7.).

A central liability issue as to defendants Hughes and Genesis, therefore, is what the standard of care required by way of PGD testing at the time of the events that have triggered this lawsuit.

At the time in question, only RGI was regularly doing multiplex testing for cystic fibrosis in the United States. Literature in Europe suggested that this technique was promising, but the average reasonably prudent PGD lab in America was not performing such testing. None of the other PGD labs in America were

utilizing this technique, including the two (2) which were most prominent, Genesis and Reprogenetics in New Jersey. (Ex. 6 at ¶ 10.) (Ex. 2 (Deposition of Mark R. Hughes, dated 5/14/10) at 49:17 - 54:20.).

Defendant Hughes has explained why his laboratory had not moved to multiplex testing in 2004:

> Q: And the use of linkage analysis certainly increases the accuracy and reduces the risk of misdiagnosis, isn't that true?
>
> A. Not in 2004. It was just beginning to be proven to be so, and the manuscripts were beginning to come out showing that it worked.
>
> Q. When you say they were beginning to come out, we do agree that Dresen's (sic.) group in Europe was reporting in 2001 the success rate for using linkage analysis, weren't they?
>
> A. They were taking two cells in order to get those results, so they were biopsying a couple of cells from each embryo. Most of the clinics we work with don't want to do that, including NYU. And the group in Chicago that was doing it was biopsying a polar body, oftentimes a first polar body and a second polar body in a blastomere.
>
> Q. Is that in all compound heterozygous cases?
>
> A. I don't know. But that was their standard that they reported in meetings and in their papers. And they argued in meetings that this was a better approach. And this was all kind of coming out. But we had a 1.2 percent error rate, which was significantly less than anybody else was reporting, so – and we were having difficulties getting multiplex PCR to make it better. *Theoretically we could see where it was quite valuable*, but we were not happy with the results, in those early papers we weren't able to reproduce them.
>
> Q. When you say you were not happy with the results, what do you mean by that?

> A. *Well, in anything in science and medicine, a manuscript comes out, and this doesn't suddenly make it the gold standard of practice. Because if it was a gold standard of practice, that paper wouldn't even be allowed to be published because it isn't new or exciting.* So the papers that were coming out in 2001 were theoretical to start with, then they became one or two cases, take a couple of cells, do the analysis and see what the results are.
>
> (Ex. 2 (Deposition of Mark R. Hughes, dated 5/14/10). Emphasis added.

Neither Strom nor Cutting is familiar with the standard of care as it existed in early-to-mid 2004 for PGD; and neither is otherwise qualified by knowledge, skill, experience, training or education to testify about the state of the art of PGD at the times pertinent to this case. The following references to their depositions are undisputed facts relevant to their lack of qualification:

DR. CHARLES STROM

1. Strom stated in his deposition that as of 2004, there were no more than eight (8) laboratories in the United States that were performing PGD: 1) RGI, in Chicago; 2) Genetics and IVF, in Virginia; 3) Cornell Medical Center, in New York City; 4) Genesis Genetics, in Detroit; 5) Reprogenetics in New Jersey; 6) Shady Grove, in North Carolina; 7) Baylor University; 8) a lab whose name he does not know, in Florida. (Ex. 1 at 112:7-8, 15-16, 18-23; 113:2-16.).

2. Strom testified that except for Genesis, which he knows from the discovery in this case was not doing multiplex testing in 2004; he does not know if any of the other labs mentioned above were doing multiplex testing. (Ex. 1 at 122:2-23.).

3. The only lab Strom knows "for sure" that was doing testing with multiplex genetic markers in 2004 was RGI; and he is not specifically aware of any other lab that was using this technology at the time. (Ex. 1 at 84:25, 85:1-10.).

4. Strom asserted that in 2004, RGI, which he believed to be doing multiplex testing, was "providing probably over half the services for PGD in the country at the time." Deposition, 5/4/2010, p. 121. The fact that is undisputed is that Strom made this assertion, not that it is true, nor that the volume any given lab has in any way governs the standard of care. (Ex. 1 at 121:7-20.).

5. Strom testified that when he was connected with RGI, from 1992 to 2000, he was the person doing PGD for that institution. During that "eight-year span," he performed "probably a couple of hundred" PGD analyses for cystic fibrosis. (Ex. 1 at 50:21-25, 51:1-3.).

6. Strom testified that these PGD analyses resulted in "probably thirty births, I would guess. Thirty to forty births." (Ex. 1 at 51:4-9.)

7. Per contra, Genesis has done 582 PGD cycles or tests in the calendar year 2004 alone. Deposition 5/4/2010, pp. 43-45; and, by way of example, performed "almost twice that" in 2009. (Ex. 2 at 43:10-25, 44:1.).

8. Strom testified that he is currently employed by Quest Diagnostics. He started working at Quest in October, 2000. (Ex. 1 at 20:12-20.).

9. Strom testified that neither he nor Quest has been engaged in PGD during the time that he has been employed there. (Ex. 1 at 22:18-22, 26:3-6.).

10. Strom testified that he teaches "everything genetics" at University of California San Diego ("UCSD"), that he "sometimes" touches on PGD in his lectures at UCSD, and that his teaching involving PGD is "probably less than five percent." (Ex. 1 at 22:23-25, 23:1-14.) (Ex. 1 at 23:15 - 25, 24:1 - 18.).

11. Strom testified that while "some" of his lecturing outside of teaching involves PGD, this percentage is about two to three percent. (Ex. 1 at 22:23-25, 23:1-14.) (Ex. 1 at 23:15 - 25, 24:1 - 18.).

12. Strom testified that he has given about a dozen depositions, but none in PGD or IVF cases, nor has he given a deposition in any case involving cystic fibrosis. (Ex. 1 at 16:24-25,17:1-16.).

13. The only wrongful birth case in which Strom has testified involved serum screening, an issue not involved in this case. Deposition, pp. 17-18. He has, therefore, never been certified or deemed qualified by a court to testify as an expert as to issues involving PGD. (Ex. 1 at 17:17-25, 18:1-3).

14. Strom testified that in formulating his opinions as to the alleged breach of the standard of care by defendants Hughes and Genesis, he does not limit his definition of that term to the United States. (Ex. 1 at 69:23-25, 70:1-9.).

15. The only materials Strom has reviewed in preparation for formulating his opinions in this case are the records of Genesis, and transcripts of the depositions of Hughes, Cutting, and Xu. He has not been provided with the records of NYU, or with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and the various NYU personnel. (Ex. 1 at 8:12-25, 9:1-7, 13:20-25, 14:1-25, 15:1-25, 16:1-6). (Ex. 3 at 166:4-19.).

DR. GARRY CUTTING

1. Cutting is a liability expert retained by the plaintiffs to offer opinions primarily against NYU; but he has additionally offered opinions critical of defendants Hughes and Genesis. (Ex. 4 at 10:18-25, 11:1-23.).

2. By way of education, background and training, Cutting is a board certified pediatrician. His fellowship training is in medical genetics, which involves the "care, diagnosis. . . and treatment of patients with a variety of genetic disorders." This is to be distinguished from PGD, which is concerned with the prevention of such disorders before implantation of embryos in an in vitro fertilization setting. (Ex. 4 at 10:18-25, 11:1-23.).

3. Cutting is not now involved directly in performing PGD. (Ex. 4 at 117:12-25.).

4. Cutting was not directly involved in performing PGD in the year 2004. (Ex. 4 at 118:1-11.) .

5. In his entire career, Cutting has been directly involved in only two (2) PGD cases, which took place "[p]robably more than 12 months ago, but not more than three years ago." (Ex. 4 at 117:12-25, 118:1-25, 119:1-7.).

6. At the time of his deposition, Cutting believed that there were two (2) or three (3) labs in the United States doing PGD. (Ex. 4 at 117:12-25, 118: 1-25, 119: 1-7).

7. Cutting has never been a member of the PGD International Society or any PGD group of scientists in the United States, Canada, or elsewhere in the world. (Ex. 4 at 146:18-23).

8. Cutting is aware that Reproductive Genetics Institute ("RGI") was doing multiplex testing for cystic fibrosis in 2004; but he does not know what was being done by Reprogenetics in New Jersey or by Cornell Medical Center in 2004, and he had never heard of Genetics and IVF in Virginia. (Ex. 4 at 156:3-25, 157:1-25, 158:1-4).

9. Cutting does not know whether in early to mid-2004, the average PGD provider in the United States with reasonable skill and care was using genetic markers for testing for cystic fibrosis in individuals undergoing. (Ex. 4 at 161:10-25, 162:1-21).

10. The only materials Cutting has reviewed in preparation for formulating his opinions in this case are the records of Genesis; the records of NYU; various articles; and transcripts of the depositions of Hughes, Licciardi, and Adler. He has not been provided with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and various other NYU personnel. (Ex. 4 at 50:2-22).

11. Cutting testified that the standard of care did not require that polar body biopsy be done or offered by defendants Genesis or Hughes in 2004. (Ex. 4 at 181:6-25; 182:1).

12. While Strom is an eminent laboratory scientist and board certified pediatrician, he has not been actively involved in PGD for nearly ten (10) years, nor has he taught the subject in an academic setting or lectured on it otherwise, other than in passing.

13. Dovetailing with this lack of experience is the fact that Strom is not familiar with the standard of practice for PGD in the United States, either as of 2004 or now, because he has no idea what the various laboratories which perform PGD were doing then or are doing now, other than his former employer, RGI, or Genesis through discovery in this case. Not only is Strom not familiar with what other labs were doing in 2004—or at present—through his work, he has not been provided with any materials to give him knowledge as to what labs other than Genesis were doing in 2004.

14. While Cutting is an eminent laboratory scientist and board certified pediatrician, he is not actively involved in PGD, nor was he so involved at or before the time of the occurrence that is the subject of this case. In fact, his only direct involvement in PGD consists of his handling two (2) PGD cases between 2007 and 2009, years after the practice of PGD had significantly evolved. Cutting has not taught the subject of PGD in an academic setting or lectured on it otherwise, other than in passing.

15. Additionally, Cutting is not familiar with the standard of practice for PGD in the United States, either as of 2004 or now, because he has no idea what the various laboratories which perform PGD were doing then or are doing now, other than RGI, or Genesis through discovery in this case and perusal of a packet of materials about RGI which were apparently provided by plaintiffs' counsel. Not only is Cutting unfamiliar with what other labs were doing in 2004—or at present—through his work, he has not been provided with any materials to give him knowledge as to what labs other than Genesis and RGI were doing in 2004.

ARGUMENT

Applicable Legal Standards

The admissibility of expert opinion is governed by Fed. R. Evid. 702, which provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

As this Court recently explained, Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Mercedes-Benz U.S.A. LLC v. Coast Auto Group, Ltd.*, 99-3121(WHW), 2006 U.S. Dist. LEXIS 71953, at *29 (D.N.J. Sept. 29, 2006), citing, *e.g. Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Expert testimony that does not meet *each* of these restrictions must be excluded. "[T]he district court is mandated the role of gatekeeper, assuring that opinion testimony that does not meet the requirements of qualification, reliability and fit [is prevented] from reaching the jury." *Mercedes-Benz*, 99-3121(WHW), 2006 U.S. Dist. Lexis 71953, at *31. This gatekeeping function applies to all expert opinion, including "engineers and other experts who are not scientists." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). There can be no dispute that the "gatekeeping" requirement mandated by Rule 702 applies to Strom and Cutting, who are primarily pediatricians. Strom has not been active in the practice of PGD since 2000, long before the events took place that are the subject of this case. Cutting, who is also a geneticist, has never been a PGD practitioner other than two brief forays into the field, the first of which was at least

three (3) years after the events occurred in this case—and after the standard of care in the United States in PGD changed markedly in the interim.

The burden to demonstrate the admissibility of expert opinion rests with its proponent to show by a preponderance of the evidence that each of the three criteria have been met. See *United States v. Schiff*, 538 F. Supp. 2d 818, 834 (D.N.J. 2008), citing *Daubert*, 509 U.S. 579; *Mercedes-Benz*, 99-3121 (WHW), 2006 U.S. Dist. LEXIS 71953, at *32; *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 526 (W.D. Pa. 2003).

As to the criterion of qualification, Rule 702, *supra*, sets forth as a threshold requirement that before he or she can offer opinion testimony on an issue, a proposed expert must be so qualified by virtue of "knowledge, skill, experience, training, or education." It logically follows that if an expert testifies about the standard of care or practice in a case involving health care, he or she must have knowledge of the standard of care as it existed *at the time in question*; and he or she must actually know what the standard is — i.e., whether it is a local standard or a national standard, and what conduct it requires. The qualification analysis is multifactorial; and the trial court deciding the issue has the duty and ability to exercise its discretion in making the decision. See *Heller v. Shaw Indus*, 167 F.3d 146, 151 (3d Cir. 1999).

Regarding the reliability requirement, expert opinion must "be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Mercedes-Benz*, 99-3121 (WHW), 2006 U.S. Dist. Lexis 71953 at *30, citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). "[A] district court must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.* 167 F.3d 146, 153 (3d Cir. 1999).

With respect to "fit," Rule 702 requires that the opinion must fit the issues in the case. "In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Mercedes-Benz*, 99-3121 (WHW), 2006 U.S. Dist. Lexis 71953 at *30-31, citing *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). A proposed expert opinion based on factual assumptions not present in the case cannot be said to assist the trier of fact because "[t]his type of opinion misleads the factfinder and arguably does not comply with the 'fit' requirement." *Id. a*t *37, citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000).

Accordingly, the Third Circuit has cautioned against the admission of an expert opinion without sufficient factual predicate, referring to such opinion as a "castle made of sand." *Id.* at *36, citing, *e.g.*, *Elcock v. Kmart Corp.*, 233 F.3d at 755; *see also Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen indisputable record facts contradict or otherwise render the [expert] opinion unreasonable, it cannot support a jury's verdict."). When a plaintiff fails to produce, by expert testimony or otherwise, sufficient competent evidence in support of an element required to be proven at trial, summary judgment is required. *Soldo*, 244 F. Supp. 2d at 526.

I. THE OPINIONS OF PLAINTIFFS' RETAINED LIABILITY EXPERTS SHOULD BE STRUCK BECAUSE THEY ARE NOT RELIABLE AS TO THE ALLEGED GENERAL ACCEPTANCE OF MULTIPLEX TESTING IN THE PGD COMMUNITY IN THE UNITED STATES IN EARLY-TO-MID 2004.

PGD is a highly dynamic, rapidly evolving field of scientific endeavor. Today's standard practice is tomorrow's version of the Model T, and tomorrow's methodologies will be obsolete next year. This case is somewhat unique in terms of *Daubert* analysis in that in the typical *Daubert* situation, a technology or

methodology which has at least arguably not yet gained general acceptance is reviewed by the courts while it is still in its infancy.

The issue in this case is what the level of acceptance of multiplex testing was on the dates pertinent to the issues in this case *for the purpose of establishing the standard of care.* In the case at bar, the technology of multiplex testing became widely accepted and used after the date in question in the lawsuit, but before the case came to court. Interestingly, this technology is becoming outdated as more sophisticated and accurate means of analysis are being developed.

Therefore, the Court must analyze whether Plaintiffs' experts are qualified to opine not on the merits of multiplex testing, *per se*, but rather on whether Plaintiffs' experts are qualified to opine on *when* the "scientific principal" of multiplex testing "crosse[d] the line between the experimental and demonstrable stages," or, to put it more bluntly, when it was that multiplex testing became the standard of care required of PGD laboratories in the United States. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

It is important at the outset to understand that the standard of care is a national one. It is the law in New Jersey and virtually everywhere else that if the care and treatment in question is in any way specialized, which PGD surely is, then the standard is a national one. "National" means exactly what one would expect: A specialist, whether practicing in New York City, Detroit, or a rural geographic area is held to the standard prevailing *throughout the United States*. The health care practitioner cannot escape liability by saying that he lacks access to information about his specialty because he or she resides in, say, Victor, Montana. Likewise, the specialist may not shield himself or herself from professional responsibility because the average practitioner in the same area of health care in South America or Africa is not as well-trained or well-equipped as he or she is. On

the other hand, if Europe is ahead of the curve in an area of the healing arts, the American specialist cannot be held to the higher European Standard.

New Jersey CHARGE 5.50A, Option A, reads in pertinent part as follows:

> The defendant(s) in this case is (are) a medical specialist(s) in the field of [*insert appropriate specialty description*]. Specialists in a field of medicine represent that they will have and employ not merely the knowledge and skill of a general practitioner, but that they have and will employ the knowledge and skill normally possessed and used by the average specialist in the field.

This New Jersey jury instruction does not explicitly say that the standard in the field is national, rather than international, but the issue is addressed in *Clark v. University Hospital-UMDNJ et al.*, 390 N.J. Super. 108; 914 A.2d 838 (App. Div. 2006). In *Clark*, the court was faced with the issue of whether a resident in surgery should be held to the standard of care for specialists in the field in which he or she practices, or whether the locality rule should be applied. In deciding that the more stringent specialty standard should be applied, the court cited with approval the Michigan case of *Bahr v. Harper-Grace Hosps.*, 198 Mich. App. 31, 497 N.W.2d 526, 528 (1993), *rev'd in part on other grounds*, 448 Mich. 135, 528 N.W.2d 170, 171 (1995), stating that "[a]lthough the applicable standard of care for general practitioners is that of the local community or similar communities, the standard of care for a specialist is *nationwide*." (emphasis added).[1]

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[1] As the reference to a Michigan case in *Clark*, *supra*, suggests, Michigan was a pioneer in departing from the old "locality rule" to establish a national standard of care for health care providers who offer specialized services. In *Naccarato v. Grob*, 384 Mich. 248, 253 (1970), the Michigan Supreme Court rejected the locality rule as to a pediatrician who failed to perform a nationally recognized PKU test, which was used nation-wide to diagnose and cause to be treated a certain form of retardation, citing with approval *Wood v. Vroman*, 215 Mich.

Without question, the plaintiffs have the burden of proof on the issue of the state of the art as it pertains to the standard of care. See *United States v. Schiff*, 538 F. Supp. 2d 818, 834 (D.N.J. 2008), citing *Daubert*, 509 U.S. 579; *Mercedes-Benz*, 99-3121 (WHW), 2006 U.S. Dist. LEXIS 71953, at *32; *Soldo*, 244 F. Supp. 2d at 526. Equally without question, they have failed as a matter of law to meet this burden.

Both of the retained experts, Strom and Cutting, admit that they are not familiar with what labs other than Genesis and RGI, which formerly employed Strom, were doing in the performance of PGD tests.

Strom was asked to provide a list of providers which, in 2004, were performing PGD testing. He then gave the following testimony:

> Q. As of early to mid 2004, without guessing or making assumptions, which of the following labs were doing genetic marker testing for cystic fibrosis: R.G.I. in Chicago?
>
> A. Yes.
>
> Q. Reprogenetics (sic.) in New Jersey?
>
> A. Don't know.
>
> Q. Genetics and I.V.F in Virginia?
>
> A. Don't know.
>
> Q. Cornell Medical Center in New York?
>
> A. Don't know.
>
> Q. Genesis Genetics?
>
> A. Don't know. Oh, no. Genesis wasn't. He said he wasn't.

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449 (1921) in stating at p. 253 that "[a]lmost 40 years ago this Court recognized the burgeoning *national community* of specialists." (emphasis added.)

Q. Shady Grove?

A. No.

Q. No, you don't know; or no, they weren't?

A. No, I don't know.

Q. Baylor?

A. Don't know.

Q. And the lab in Florida we talked about?

A. Don't know.

Deposition, 5/4/2010, pp. 121-122.

It is interesting at the outset to note that Cutting is and always was so far removed from the PGD community in the United States that at the time of his deposition, he believed that there were two (2) or three (3) labs in the United States doing PGD.

Q. How many labs in the country do PGD testing?

A. Two or three. As far as I know.

Deposition, 4/24/2010, p. 123.

Asked specifically about labs other than RGI in Chicago and Genesis Genetics, Dr. Cutting displayed a similar lack of knowledge and familiarity.

Q. Do you know Repro Genetics in New Jersey, Dr. - -

A. I don't know.

Q. Do you know whether - - you said you never heard of Genetics and IVF in Virginia?

A. No, not really. No, no. I mean that's not one I think about, I think of just Repro and - -

> Q. So you don't know?
>
> A. No, no.
>
> Q. Or Cornell Medical Center in - -
>
> A. I don't know if Wells was doing it, I don't know, I don't.
>
> Q. Do you know how many of these labs besides maybe RGI were using genetics (sic.) markers at all, let alone in testing for cystic fibrosis?
>
> A. I - - I know it was indicated that it's good to use it for causes. I don't - - I don't know for sure, no, I don't. But I think this is all discoverable. You could certainly ask these laboratories.
>
> Deposition, 4/24/2010, p. 157.

Cutting was "under the impression" that Reprogenetics was doing genetic marker testing for cystic fibrosis in 2004. In fact, it was not—Reprogenetics was using FISH testing (see below for more information on this subject). Pressed on his actual knowledge, Cutting was candid enough to admit that this "impression" did not amount to knowledge to which he could swear.

> Q. Do you *know* whether in the early to mid - - in early to mid-2004, the average PGD provider with reasonable skill and care was using genetic markers for testing for cystic fibrosis in individuals undergoing preimplantation genetic diagnosis?
>
> A. The average - -
>
> Q. And that's in the United States?
>
> A. So if it were two out of four, I think probably, yeah, two out of four would do it. Because I'm under the impressio (sic.) Repro was doing it. I'm under the impression one of the other labs was doing it because their presentation I recall seeing. I know RGI was doing it and I believe, at least, one other lab. So that's an average of two out of four, so that's average, yeah.

Q. *Do you know whether?*

A. *Do I absolutely know?* No. *You asked my impression.*

Deposition, 4/24/2010, pp. 161-162. (emphasis added).

In fact, the only lab in the United States that was routinely doing multiplex testing for cystic fibrosis in early-to-mid 2004 was RGI, in Chicago. See Declaration of Dr. Mark R. Hughes, Ex. 6.

Strom tried to salvage the validity of his opinion that multiplex testing should have been standard of care in 2004 by asserting that in terms of volume, his laboratory was doing more than half of the PGD in the United States in cases involving cystic fibrosis. In the first place, this analysis flies in the face of the clear language of the law regarding the standard of care. New Jersey law, just for example, makes reference to "the *average specialist* in the field," not the average procedure that is done. New Jersey CHARGE 550.A.

Additionally, this assertion is simply not true. As noted above, Strom testified that these PGD analyses resulted in "probably thirty births, I would guess. Thirty to forty births." Deposition, 5/4/2010, p. 51. On the other hand, Genesis Genetics has done 582 PGD cycles or tests in the calendar year 2004 alone. Deposition 5/4/2010, pp. 43-45.

Moreover, the argument that the number of procedures done governs the standard makes no logical sense. There is absolutely no correlation, empirical or otherwise, between volume and quality in medical testing. The number of procedures done by an institution has as much to do with its geographical community and its entrepreneurial skill as anything else.

Strom and Cutting both offer European literature in combination with the RGI experience to assert that multiplex testing *should have been* required by the standard of care in 2004. Again, the standard is not always (or even often) what

may be viewed at the time to be the optimum—it is what is actually done by capable, educated, trained and experienced people in the mainstream.

Further, the European literature relied upon by Strom and Cutting to support their positions is not admissible under FRE 401, which provides as follows:

> "Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

By definition, literature about what Europeans are doing cannot establish what the reasonably prudent PGD lab is doing in America, so it is irrelevant because it does not tend to support such a proposition.

Additionally, if such literature has some probative value that we are missing in this analysis, then FRE 403 dictates that such evidence should be excluded because its probative value, if any, is outweighed by the danger "of unfair prejudice, confusion of the issues, or misleading the jury."

As noted above, the plaintiffs have abjectly failed in their burden of proof to show that multiple cell testing was the accepted mainstream approach in early to mid 2004. And they have failed not only because they have fallen short in their proofs, but because in fact the technology they urge as being the standard was not in wide acceptance in the United States at the time. Was multiplex testing on its way to its place in the sun in PGD in America? Yes. Was it there yet? No.

There is an "erudition curve" between the germination and early development of a scientific or technical idea and its practical use and acceptance in the real world. The first patent on a jet engine was issued in the late 1930s. The Germans were the first to fly jet aircraft near the end of World War II, in 1945. When was commercial jet travel the norm? No earlier than 1959 or 1960, fourteen

years after the end of World War II and more than 20 years after the jet engine was patented.

Not only is the road to mainstream use of a methodology or technology bumpy at times, there are often wrong turns people can take if they are not extremely cautious, as Hughes was. There was a technology called FISH (fluorescent in situ hybridization) that was briefly in vogue in the PGD community. For awhile it was in widespread use, particularly at RGI. The experience with FISH is instructive. Per Hughes' deposition:

> Q. Okay, so then using [multiplex] technique as a standard use in their laboratory, RGI was doing it, they had the technology, didn't they?
>
> A. We had the – lots of people have the technology. The question was, was it ready to be added and was it proved to be useful and was it better.
>
> Q. Well, if it reduced the - -
>
> A. Let me give you an example. The same group who I think are outstanding in Chicago, Svetlana Rechitsky and Buck Strom, they were great scientists, they were working on a technology called FISH. And when you quote these numbers from Cornell with thousands of cycles, those were done with FISH. In fact, the world jumped on the ability to count chromosomes using FISH technology. And now, all of the medical societies that oversee this have said that there's no scientific evidence that this works. There's no scientific evidence that a patient should have FISH testing. And it's written in the practice guidelines of the field by the authorities who you would recognize that direct the way that something is performed in medicine. In the society's guidelines of practice it says that there's no scientific evidence that FISH works. Now, it's controversial. We never believed in that technology either, and never performed it. Why? Because we couldn't get it to work with the kinds of reliability we wanted. In the same way in IVF, there's all sorts of steps that are taken to try to improve

> the technology an (sic.) get people pregnant with healthy babies. It's done all the time. Many of these fall by the way side (sic.) as being not helpful, can't be reproduced. So in the first few years of (sic.) the year 2000 people started talking about doing this in PGD, and everybody, I would hope, was trying to get this to work because of the theoretical idea that it was going to help and avoid one of the problems with PGD, which is allele drop out. But you have to have a technique that improved it significantly more than what you already had. No more than Memorial Sloan Kettering invents a new cancer agreement (sic.) and no other cancer programs in the country use it for some five years or ten years while they're assessing it. It doesn't make it standard, just because you publish a paper, doesn't make it standard of care. Hughes deposition, 5/14/2010, pp. 52-54.

The foregoing is an excellent illustration of why the standard of care is not defined by what the avant garde are practicing, nor by what a particular witness does in his or her practice.

We have seen from the Declaration of Dr. Mark R. Hughes, Ex. 6, that only one PGD laboratory in the United States, RGI, was doing multiplex testing for cystic fibrosis. Necessarily, then, multiplex testing was not the standard of care.

To the extent that they claim multiplex testing was the standard of care in early-to-mid 2004, Strom and Cutting are unreliable in their testimony. They rather candidly admit that they simply do not know what labs other than Genesis and RGI were doing at the time in the United States. Accordingly, their testimony, reports and opinions as to standard of care should be struck.

II. THE OPINIONS OF DRS. CHARLES STROM AND GARRY CUTTING SHOULD BE STRUCK BECAUSE THEY LACK QUALIFICATION TO TESTIFY AS TO THE STANDARD OF CARE FOR THE PERFORMANCE OF PREIMPLANTATION GENETIC DIAGNOSIS IN EARLY-TO-MID 2004.

Strom is unqualified to testify as to the standard of care applicable to PGD for two reasons. First, he does not understand and agree that either the standard of care is local or national, and not international. Second, as referenced above, he is admittedly without knowledge as to whether the average PGD laboratory in the United States was doing single cell PCR or multiplex testing at the time in question in this case.

This lack of knowledge comes from a lack of foundational basis. As mentioned in the statement of facts, above, Strom readily acknowledged that he has not been involved in a hands-on capacity in PGD since October, 2000; nor has he taught it to any significant degree ("probably less than five percent" of the time he has spent teaching courses and residents in pediatrics).

Cutting has likewise readily acknowledged that he is not currently involved in a hands-on capacity in PGD, and that his first two (2) *and only* direct experiences with PGD occurred between 2007 and 2009. Similarly, Cutting has not taught PGD per se.

While some courts have determined that under certain circumstances, the lack of either current hands-on experience in a field, or such experience concurrent with the date of the incident, is not necessarily fatal to qualifying an expert to testify, it is likewise clear that such experience is an important stone in the balance scale to weigh in determining whether an expert is qualified.

In his deposition on May 4, 2010, Strom was asked about his experience as an expert witness in areas similar to those in this case. The short answer is that he has none.

> Q. How many depositions have you given before today?
>
> A. Maybe a dozen or so.
>
> Q. As an expert witness?
>
> A. Some as an expert witness, some in criminal trials as an expert witness, so all as an expert witness.
>
> Q. So you've given about a dozen depositions?
>
> A. Give or take, yes.
>
> Q. *Have any of those been P.G.D. cases?*
>
> A. *No.*
>
> Q. *Have any of the cases where you've given depositions been non P.G.D., non I.V.F. cases involving cystic fibrosis?*
>
> A. *No.*
>
> Deposition, 5/4/2010, pp. 16-17. (emphasis added).

This case is, of course, all about the application of IVF and PGD to cystic fibrosis and its prevention. While Strom is knowledgeable about cystic fibrosis, and while he was involved in PGD years before the events that gave rise to this case, he is undoubtedly absolutely bereft of expert testimonial experience in *any* of these areas, let alone the synergy of the three. While testimonial experience is not by itself the *sine qua non* of whether a person can testify as an expert witness, its importance is enhanced if the witness is not active in hands-on practice of the discipline about which he renders his opinions.

In fact, Strom has a fundamental lack of knowledge of, and respect for, what is involved in testifying as a liability expert in an action alleging professional responsibility—and what is involved in the preparation therefor. Excluding the two-part deposition of Strom himself, there have been twelve (12) depositions taken of ten (10) other witnesses in this case. These deponents have included both of the adult plaintiffs and five (5) employees of the defendant NYU. Although he has rendered opinions as to the state of mind of the Grossbaums, what they knew and did not know, their decision-making processes, and the process by which the implanted embryos were chosen *at NYU*, Strom has not availed himself of transcripts of any of these depositions, nor of any of the records of NYU. (See Deposition, 5/4/2010, p. 135.)[2]

How does he account for this glaring lack of responsibility as an evaluating expert? Well, in a cavalier manner.

> Q. And if I were to tell you that before the expert part of this deposition (sic.), there were nine depositions of (sic.) this case there were nine depositions taken in this case. You've read one of these depositions, correct? The one of Dr. Hughes?
>
> A. Two. And the one from Dr. Cutting.
>
> Q. That was a tenth deposition; of the other eight, various other N.Y.U. employees and the Grossbaums, you haven't read any of those depositions.
>
> A. That's correct.
>
> Q. You haven't asked for any of those depositions.

[2] This failure is not simply illustrative of a deficient attitude, it is material to this case. Both Strom and Cutting have opined that the Grossbaums were not well informed of the nature of PGD; as will be seen from the motion by defendants Hughes and Genesis for summary judgment, the depositions of the plaintiffs belie this assertion.

> A. That's correct.
>
> Q. And you're telling us you didn't suspect that others were deposed in this case, even though N.Y.U. is a party defendant?
>
> A. It's none of my business.
>
> Q. What is your business, then? How would you define it in this case?
>
> A. I was asked to give an opinion based on these facts and I was sent a packet and I reviewed it and gave my opinion.
>
> Q. As a scientist, don't you want to know the entire universe of what might comprise that opinion?
>
> A. I know that there's a difference between law and science and in law, you do what you're told.
>
> Deposition, 5/4/2010, pp. 15-16. (emphasis added).

This flippant expression of fundamental misunderstanding of his role as an expert was reiterated later in the deposition. After Strom acknowledged familiarity with the parable of the several blind men feeling an elephant and the one handling the trunk believing the beast to be a snake, the following exchange ensued:

> Q. Were you satisfied as a scientist in your role at only finding the snake and ignoring the larger picture of what was going on with the Grossbaums in the P.G.D. I.V.F. endeavor that resulted in the birth of Rosie Grossbaum?
>
> A. I was asked to do a task. I reviewed the materials I was sent and did my task.
>
> *This is not a scientific endeavor, this is a legal endeavor and in my experience they're mutually exclusive.*
>
> Deposition, 5/4/2010, pp. 138-139. (emphasis added).

In short, Strom lacks any meaningful experience as an expert in cases of this nature; and he is certainly bereft of any experience in testifying with regard to the

subject at hand. As a result, he sees himself—cynically or otherwise—as a partisan advocate who invokes science or scientific methods only to the extent that it suits his marching orders and his self-perceived role to do so. This sort of intellectual sloppiness was addressed in *Kumho, supra,* at 152,

> [T]his is not to deny the importance of *Daubert's* gatekeeping requirement. The objective of that requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, *employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.* (emphasis added).

For *Daubert* purposes, science and law are not, as Strom says, "mutually exclusive." They are one and the same.

It is an understatement to say that Strom's analysis of the facts and circumstances employs limited "intellectual rigor." It employs virtually none; and even though Dr. Strom was put on notice in the May 4, 2010 deposition that the probity of his analysis was going to be challenged, he did not acquire and read any of the above-mentioned deposition transcripts, nor the NYU records, between that session of his deposition and the conclusion of his deposition on June 24, 2010.

This failure of scientific intellectual rigor by Strom is not just important as an general means of pointing out his shortcomings, it has practical application. Strom assumes that the Grossbaums were compliant in the IVF/PGD process, when in fact, they had sexual relations throughout the process, including within days before the implantation. This information is contained in the NYU records and their depositions; but Strom never availed himself of either of these important sources. Likewise, Strom makes the assumption that Hughes bullied the Grossbaums into agreeing to prenatal testing, when in fact the testimony of the

Grossbaums is that they agreed to such testing with the full knowledge and conviction that they would never undergo it.

Unlike the combative Strom, Cutting has candidly acknowledged that this case is not really in his wheelhouse as an expert.

> Q. Have you ever been a member of the PGD International Society or PGD group of scientists in the United States or Canada?
>
> A. No.
>
> Q. Or anywhere in the world?
>
> A. No.
>
> Q. Is it fair to say that while you're an expert in cystic fibrosis that you are not an expert in PGD?
>
> A. I'm an expert in genetic diagnostics, and this is a genetic diagnostic test.
>
> Q. So you're an expert in the G D but not the P?
>
> A. Yes. Thank you.
>
> (Laughing.)__
>
> Q. All right.
>
> A. I agree with you.
>
> Deposition, 4/24/2010, pp. 146-147.

Further, Cutting has testified that his fellowship training in medical genetics did not involve any *preimplantation* involvement, but rather the counseling of either patients already afflicted with congenital conditions, or women pregnant with fetuses known to be affected.

> Q. Okay. Now, after your - - your residency in pediatrics you completed a fellowship, correct?

A. Correct.

Q. Okay. We'll - - what did that - - strike that. What was the concentration of that fellowship?

A. Genetics, medical genetics.

Q. Can you be - - be more specific? Tell me exactly sort of what that entails?

A. Well, patients whose disease is primarily caused by abnormalities in specific genes.

Q. Okay. Yeah, I'm just trying to get an idea sort of what kind of things did you do? I mean, did you - -

A. I would be consulted on patients who were, where the physicians felt that there would be a genetic case because a familial recurrence of children in the same family. So, like CF, two children same family have the disease, so we get consulted for that. We get sickle cell disease. We get consulted for skeletal abnormalities - -

Deposition, 4/24/2010, pp. 10-11.

* * *

Q. Okay. Now - - okay. So, what specific function did you Do during your fellowship as it pertains to, um, prenatal involvement with patients?

A. So we would counsel patients who had prenatal conditions. We would see patients who had undiagnosed prenatal conditions where there was concern. We would see women who had advance maternal age, which I'm sorry to say, is beyond 35 years of age who have were at higher risk for children with abnormalities, such as Down Syndrome.

If I'm going too fast, please tell me to slow down.

It would be working with families to tell them about the results of test, such as sider genetics tests or - - or DNA based tests and the results and counseling them on those results. With

> working with them to make decisions about whether to continue the pregnancy, particularly if the pregnancy was affected.
>
> Q. And that was during your fellowship?
>
> A. That was during my fellowship *and I continue to do that.* That's why I'm carrying the beeper today, if this condition came up today at Johns Hopkins, I would be called for it and I would go in and talk to them.
>
> Deposition, 4/24/2010, pp. 12-13.

In discussing the fact that the above is markedly different from the practice of PGD, Cutting candidly acknowledged the scope of the differences and the fact that PGD is *by far* more exacting and challenging that what he does in his lab.

> Q. How is PGD different from what you routinely do in your lab?
>
> A. If we're talking about blastomere biopsy which the removal of one cell or two, depending on which lab you do and how you do it, it involves a much smaller amount of DNA and it requires exquisite levels of, um, testing ahead of time to assure that you get an accurate diagnosis, because unlike in the case, as you've been indicating, that when you get a large amount of DNA from a CVS sample or from a blood sample of a patient we're getting six pictograms of DNA on average from one cell.
>
> Q. This is in PGD?
>
> A. PGD, sorry.
>
> Q. All right.
>
> A. *So the test and the importance of being accurate and having plenty of additional assays there to be sure you achieve accuracy is absolutely paramount in PGD because it is the more challenging area of genetic diagnosis currently available.*
>
> Q. PGD is?
>
> A. Yes, *by fair* (sic.).

Deposition, 4/24/2010, pp. 114-115.

The State of Michigan has gone so far as to codify this requirement that an expert witness in the healing arts be involved in exactly the same discipline as the person against whom he or she is testifying.[3]

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[3] MCL Section 600.2169

> (1) In an action alleging medical malpractice, a person shall not give expert testimony on the appropriate standard of practice or care unless the person is licensed as a health professional in this state or another state and meets the following criteria:
>
> > (a) If the party against whom or on whose behalf the testimony is offered is a specialist, *specializes at the time of the occurrence that is the basis for the action in the same specialty as the party* against whom or on whose behalf the testimony is offered. However, if the party against whom or on whose behalf the testimony is offered is a specialist who is board certified, the expert witness must be a specialist who is board certified in that specialty.
> >
> > (b) Subject to subdivision (c), *during the year immediately preceding the date of the occurrence* that is the basis for the claim or action, *devoted a majority of his or her professional time* to either or both of the following:
> >
> > > (i) *The active clinical practice of the same health profession* in which the party against whom or on whose behalf the testimony is offered is licensed and, *if that party is a specialist, the active clinical practice of that specialty.*
> > >
> > > (ii) The instruction of students in an accredited health professional school or accredited residency of clinical research program *in the same health profession* in which the party against whom or on whose behalf the testimony is offered is licensed and, if that party is a specialist, an accredited health professional school or accredited residency or clinical research program *in the same specialty.*

(emphasis added).

We are not urging in this motion that the Michigan statute is binding; however, it employs the sort of strict approach that should be applied in determining whether an expert witness is qualified so that his testimony will fit the facts and circumstances of the case.

First, last and foremost, this case is about the application of in vitro fertilization (IVF) and PGD to cystic fibrosis and its prevention. Cutting has acknowledged that IVF is within the purview of obstetrics and gynecology, and not what he does in his profession. Cutting is knowledgeable about cystic fibrosis from the perspective of a laboratory and clinical medical geneticist. And while he had passing involvement with PGD years after the events that gave rise to this case, such involvement was minimal, and it was years after the technology involved in PGD had markedly evolved. With all of this in mind, it cannot be seriously disputed that Cutting is without sufficient contemporaneous experience and qualification to allow him to testify about IVF or PGD, let alone the synergy between the two.[4]

Per Rule 702, Strom and Cutting are not qualified to testify in this case because both at the time of the incident that is the subject of this case and currently, they lack "knowledge, skill, experience, training, or education" in the

[4] Additionally, Cutting has not been provided with all of the materials necessary to form the basis for all of the opinions he has expressed. Specifically, he has opined that the Grossbaums initially agreed to undergo amniocentesis or CVS but then changed their minds. In fact, they have testified that it was never their intention to undergo either of these prenatal tests, and that have both said that they communicated this state of mind to Hughes and various NYU people. This is not a major point as regards the issue of Cutting's qualifications as an expert; but it is revealing in the sense that Cutting was willing to testify about the state of mind of the Grossbaums without the benefit of their deposition transcripts or transcripts of the depositions of the various NYU people who addressed this question.

field of PGD. Moreover, it is abundantly clear from the foregoing that because they have not made adequate inquiry into the facts and circumstances of this case, their opinions and testimony are not "based upon sufficient facts or data, per Rule 702(1)." Nor are they "the product of reliable principles and methods," per Rule 702(2). And these witnesses have not "applied the principles and methods reliably to the facts of the case," per Rule 702(3). Accordingly, the opinions, reports and testimony of Strom and Cutting should be struck in this case.

CONCLUSION

For the foregoing reasons, the Court should strike in its entirety the reports, testimony and opinions of Dr. Charles Strom and Dr. Garry Cutting.

Respectfully submitted,

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